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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,268	01/25/2005	Alma Dal Pozzo	GRT/4865-42	8815

23117	7590	02/05/2008
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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/522,268

Applicant(s)

DAL POZZO ET AL.

Examiner

Jeffrey E. Russel

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

The Sequence Listing filed December 7, 2007 is objected to because SEQ ID NO:1 as defined in the Sequence Listing does not correspond to the amino acid sequence identified as SEQ ID NO:1 in the specification and claims. SEQ ID NO:1 as defined in the Sequence Listing comprises 6 amino acids, including an Asn residue. The amino acid sequence identified as SEQ ID NO:1 in the specification and claims comprises only five amino acids, none of which are an Asn residue. Note also that "Tfm" is not an amino acid residue, but rather is the abbreviation for a trifluoromethyl group, which is attached to the Phe residue.

Applicant must provide a substitute computer readable form (CRF) copy of the Sequence Listing, a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

The Sequence Listing filed December 7, 2007 was approved by STIC for matters of form.

2. Claims 1-8 and 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Because of the insertion of "and" at claim 1, line 11, it is unclear if the structure recited at claim 1, line 12, forms part of the definition of R₄. It is possible that "and" should instead have been inserted before the structure recited at claim 1, line 12. The relationship between the definition of R₄ at claim 1, lines 9-12 and 15; the definition of X₄ at

Art Unit: 1654

claim 1, line 17; and the definition of -NX₄-R₄- at claim 1, page 5 of the amendment, line 1, is unclear. It is not clear, e.g., if these definitions are alternatives to one another. It is also not clear if the text at claim 1, page 5 of the amendment, line 2, belongs to the definition of X₁-X₅ (see claim 1, line 17), or if this text forms part of the definition of -NX₄-R₄-. Claim 1, page 5 of the amendment, line 1, is unclear because if -NX₄R₄- has either of the two recited structures, then the nitrogen atom does not have an available valence for attachment to the preceding NX₃-R₃-CO residue. The proviso at claim 1, page 4 of the preliminary amendment, lines 3-4, is unclear as to whether the requirement for at least one α -fluoroalkylated amino acid can be satisfied by attachment of a fluoroalkyl group to one of the nitrogen atoms present in the cyclic peptide backbone, or whether the requirement must be satisfied by attachment of a fluoroalkyl group to one of the C α atoms. The interpretation of " α " in the proviso is uncertain. Claim 2 is indefinite because, for the first four listed compounds, it is not clear if the Tfm and Dfm groups are to be attached to the nitrogen atom of the following amino acid, or to the C α atom. Claim 2 is indefinite because the third-listed compound does not correspond to SEQ ID NO:1 as defined in the Sequence Listing filed March 13, 2006. See section 1 above.

3. Claims 1, 3-8, and 10-14 are objected to because of the following informalities: At claim 1, page 5 of the amendment, line 2, "or" should be inserted after the comma so that standard Markush language is used. Appropriate correction is required.

4. Applicant's arguments filed December 7, 2007 have been fully considered but they are not persuasive.

The same objections made to the sequence listing filed March 13, 2006 have been made to the sequence listing filed December 7, 2007. Applicants made no changes to the sequence

listing relevant to the substance of the objections, nor did they traverse the examiner's grounds of objection in their Remarks.

There was no response in Applicants' amendments or arguments to most of the rejections under 35 U.S.C. 112, second paragraph, repeated in section 2 above. With respect to the definition of α -fluoralkylated amino acid, Applicants cite to "pages 405" (sic - pages 4-5?). However, pages 4-5 of the specification do not use the term " α -fluoralkylated amino acid". As noted in the rejection, it is unclear if the " α " means that a fluoralkyl group must be attached to at least one of the C α atoms, or if attachment of a fluoralkyl group to one of the nitrogen atoms as one of the X₁-X₅ groups will also satisfy the claim requirements.

5. Claims 1-8 and 10-14 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, and the claim objections set forth in this Office action.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

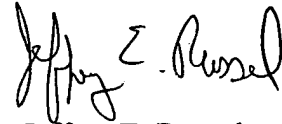
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1654

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

January 29, 2008